

**CLIA UPDATE – December 2003**  
**Division of Laboratory Services**  
**Centers for Medicare & Medicaid Services**  
 CLIA Surveys: Top Deficiencies  
 First, Second, Third, and Fourth Cycle

Regulatory Subpart	Regulatory Cite	Deficiency	All Labs				POLs			
			1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>
Quality Control (D4006)	493.1202(c)(4)	The lab must perform and document at least 2 levels of controls each day or testing.	6,361 30%	1,435 10.5%	929 6.8%	703 5.1%	4,992 35%	958 10.5%	634 7.0%	446 4.9%
Quality Assurance (D7001)	493.1701	The lab must establish and follow a comprehensive, written quality assurance program to monitor its overall operation.	5,645 27%	1,483 10.8%	1,112 8.1%	1,070 7.8%	4,266 29%	997 11.0%	703 7.7%	672 7.4%
Quality Control (D4001)	493.1202(c)(1)	The lab must follow the manufacturer's instructions for instrument operation and test performance.	5,124 24%	1,719 12.5%	1,307 9.5%	1,223 8.9%	4,050 28%	1,132 12.5%	920 10.1%	872 9.6%
Personnel (D6032)	493.1407(e)(14)	The lab director must specify in writing the responsibilities and duties of all personnel.	3,853 18%	587 4.3%	336 2.4%	288 2.1%	2,821 20%	428 4.7%	261 2.9%	201 2.2%
Quality Control (D4022)	493.1202(c)(2)	The lab must have a procedure manual.	2,903 14%	723 5.3%	454 3.3%	355 2.6%	2,219 15%	526 5.8%	360 4.0%	267 2.9%
Quality Assurance (D7047)	493.1709(b)	The lab must have a system for verifying accuracy and reliability twice each year for tests not covered under the lab's PT program.	NA	1,292 9.4%	1,023 7.5%	930 6.8%	NA	671 7.4%	607 6.7%	535 5.9%
Proficiency Testing (D6018)	493.1407(e)(4) iii	All PT reports received are reviewed by appropriate staff to evaluate lab's performance and identify any problems that require corrective action.	NA	566 4.1%	653 4.8%	554 4.0%	NA	462 5.1%	488 5.4%	415 4.6%
Proficiency Testing (D2000)	493.801	The lab must enroll in a PT program approved by HHS for each specialty and subspecialty of tests it performs.	NA	456 3.3%	249 1.8%	288 2.1%	NA	356 3.9%	168 1.8%	202 2.2%
Proficiency Testing (D2015)	493.801(b)(5)	Laboratory must keep lab proficiency records a minimum amount of time.	NA	744 5.4%	640 4.7%	653 4.8%	NA	510 5.6%	462 5.1%	438 4.8%
Total Number of Laboratories with First, Second, Third and Fourth surveys			21,224	13,715			14,391	9,084		

NA = Not Available